



Express Mail No. EV336590758USUS

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Alexander Gaiger et al.
Application No. : 09/785,019
Filed : February 15, 2001
For : COMPOSITIONS AND METHODS FOR WT1 SPECIFIC
IMMUNOTHERAPY

Examiner : Ronald B. Schwadron
Art Unit : 1644
Docket No. : 210121.465C4
Date : August 27, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT AND PRELIMINARY AMENDMENT

Commissioner for Patents:

In response to the Restriction Requirement dated May 27, 2003, please extend the period of time for response two months, to expire on August 27, 2003. Enclosed are a Petition for an Extension of Time and the requisite fee.

In response to the Restriction Requirement dated May 27, 2003, Applicants hereby further elect with traverse Group I, claims 1, 2, 6, 7, 47-55 for examination at this time. Applicants further elect with traverse, the peptide of claim 48 (p117-139). Applicants respectfully submit that it would not constitute an undue burden for the Examiner to search the polypeptide of claim 49 (p130-138) along with elected species of the peptide of claim 48, and the previously elected species of SEQ ID NO:335 as detailed further in the following Remarks. Applicants lastly elect microspheres for the immune response mediator of claim 54.

Prior to examination of the application, please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Previously Presented) A polypeptide comprising at least an immunogenic portion of an amino acid sequence of SEQ ID NO:335, or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with WT1-specific antisera and/or T-cell lines or clones is not substantially diminished.

2. (Previously Presented) A polypeptide according to claim 1 or claim 47, wherein the immunogenic portion binds to an MHC class I molecule.

3. (Previously Presented) A polypeptide according to claim 1 or claim 47, wherein the immunogenic portion binds to an MHC class II molecule.

4.-5. (Canceled)

6. (Previously Presented) A polypeptide according to claim 1 or claim 47, wherein the polypeptide comprises 4-16 consecutive amino acids of a native WT1 polypeptide.

7. (Previously Presented) A polypeptide according to claim 1 or claim 47, wherein the polypeptide comprises 8-10 consecutive amino acids of a native WT1 polypeptide.

8.-46. (Canceled)

47. (Previously Presented) A polypeptide comprising at least an immunogenic portion of an amino acid sequence of SEQ ID NO:335, or a variant thereof that differs in substitutions at between 1 and 3 amino acid positions, such that the ability of the variant to react with WT1-specific antisera and/or T-cell lines or clones is enhanced relative to a native WT1.

48. (Previously Presented) The polypeptide of claim 1 or claim 47 wherein said immunogenic portion comprises amino acid residues 117-139 of WT1.

49. (Previously Presented) The polypeptide of claim 1 or claim 47 wherein said immunogenic portion comprises amino acid residues 130-138 of WT1.

50. (Previously Presented) The polypeptide of claim 1 or claim 47 wherein said polypeptide does not include the His tag of SEQ ID NO:335.

51. (Previously Presented) A composition comprising any one of the polypeptides of claim 1 or claim 47 in combination with a pharmaceutically acceptable carrier or excipient.

52. (Previously Presented) An immunogenic composition comprising any one of the polypeptides of claim 1 or claim 47 in combination with a non-specific immune response enhancer.

53. (Previously Presented) The immunogenic composition according to claim 52 wherein the non-specific immune response enhancer preferentially enhances a T cell response in a patient.

54. (Currently Amended) The composition according to claim 52, wherein the immune response enhancer comprises ~~is selected from the group consisting of Montanide ISA50, Seppic Montanide ISA 720, a cytokine, a microsphere, dimethyl dioctadecyl ammoniumbromide (DDA) based adjuvants, AS-1, AS-2, Ribi Adjuvant system based adjuvant, QS21, saponin based adjuvants, Syntex adjuvant in its microfluidized form, MV, ddMV, immune stimulating complex (iscm) based adjuvants, and inactivated toxins.~~

55. (Canceled)

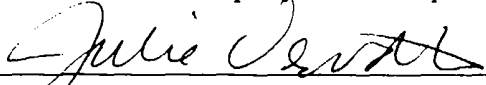
REMARKS

As noted above, Applicants hereby elect with traverse Group I, claims 1, 2, 6, 7, and 47-55 for examination at this time. Applicants further elect with traverse, the peptide of claim 48 (p117-139) and further elect the microspheres for the immune response mediator of claim 54.

Applicants respectfully request, however, that the Examiner reconsider restricting the claims to the peptide of either claim 48 or 49 and, instead, consider searching the peptides of claim 48 (p117-139) and claim 49 (p130-138) and SEQ ID NO:335 in a single application. The sequence of claim 49 (p130-138) is found within the sequence of claim 48 (p117-139) which is found within the sequence of SEQ ID NO:335, also referred to as WT_A, elected in the first restriction requirement. A search of the art of any one of these sequences would necessarily identify art related to the other two sequences. Accordingly, Applicants submit that no undue search burden would arise with respect to a search of the peptide of claim 48, in conjunction with the peptide of claim 49 or the peptide of SEQ ID NO:335.

Non-elected claims 10-46 have been canceled. In addition, claim 55 has been canceled and claim 54 has been amended solely to remove reference to non-elected subject matter. Following this amendment, claims 1-3, 6, 7, and 47-54 are under consideration. Consideration of the elected claims is now requested.

Respectfully submitted,
Alexander Gaiger et al.
Seed Intellectual Property Law Group PLLC



Julie A. Urvater, Ph.D., Patent Agent
Registration No. 50,461

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031
390152_1.DOC